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EXAMINER

HA, JULIE

ART UNIT	PAPER NUMBER
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1654

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,637

Applicant(s)

BOHLIN ET AL.

Examiner

Julie Ha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Election/Restriction requirement filed on February 27, 2007 is acknowledged. Claims 1, 9-10 and 12-14 were cancelled in the reply on February 27, 2007. Applicants amended claims 2-8 so that these claims depend on claim 11. Claims 2-8 and 11 are pending in this application.

Restriction

1. Applicant's election without traverse of Group III (claim 11) drawn to a method of using a peptide to prevent on-growth of biological organisms on objects or living beings in the reply filed on February 27, 2007 is acknowledged. Claims 2-8 were amended to depend on claim 11, thus claims 2-8 and 11 are examined on the merits in this application.

Rejection-35 U.S.C. 112, 2nd

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 2 and 11 recite a cyclotide having a general formula wherein a, b, c, d, e and f represent the number of amino acid residues in each respective sequence and each a to f may be the same or different and range from 1 to about 20 with a SEQ ID

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NO: 1 in the parenthesis. It is unclear whether SEQ ID NO: 1 is an example or if SEQ ID NO: 1 represents the cyclotide of claim 2. If the latter case is true, then it is unclear how the amino acids can be 1 to about 20, since a to f of SEQ ID NO: 1 all consist of 20 amino acid residues. This reads that a to f cannot be anything less than 20 amino acids. Thus, it is unclear which cyclotide represents the claimed invention of claim 2.

5. Claims 3 and 11 recite a cyclotide having a general formula wherein each of a to f ranges from 1 to about 10 with a SEQ ID NO: 2 in the parenthesis. It is unclear whether SEQ ID NO: 2 is an example or if SEQ ID NO: 2 represents the cyclotide of claim 3. As described supra, if the latter is true, then it is unclear how the amino acids can be 1 to about 10, since a to f of SEQ ID NO: 2 all consist of 10 amino acid residues. This reads that a to f cannot be anything less than 10 amino acids. Thus, it is unclear which cyclotide represents the claimed invention of claim 3.

6. Claims 4 and 11 recite a cyclotide having a general formula wherein each of a to f represent the number of amino acid residues in each respective sequence and wherein a is from about 3 to about 6, b is from about 3 to about 5, c is from about 2 to about 7, d is about 1 to about 3, e is about 3 to about 6, and f is from about 4 to about 9 with a SEQ ID NO: 3 in the parenthesis. It is unclear whether SEQ ID NO: 3 is an example or if SEQ ID NO: 3 represents the cyclotide of claim 3. If the latter case is true, then it is unclear how the amino acids can be as described above, since SEQ ID NO: 3 consists of a is 6, b is 5, c is 7, d is 3, e is 6 and f is 9. This reads that the amino acid residues have a set length of amino acids for a to f and cannot be anything more or less

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than a is 6, b is 5, c is 7, d is 3, 3 is 6 and f is 9. Thus, it is unclear which cyclotide represents the claimed invention of claim 3.

7. Claims 5 and 11 recite a cyclotide having a general formula wherein each of a to f represent the number of amino acid residues in each respective sequence and wherein a is about 3, b is about 4, c is from about 4 to about 7, d is about 1, e is about 4 or 5, and f is from about 4 to about 7 with a SEQ ID NO: 4 in the parenthesis. It is unclear whether SEQ ID NO: 4 is an example or if SEQ ID NO: 4 represents the cyclotide of claim 5. If the latter case is true, then it is unclear how the amino acids can be as described above, since SEQ ID NO: 4 consists of a is 3, b is 4, c is 7, d is 1, e is 5 and f is 7. This reads that the amino acid residues have a set length of amino acids for a to f and cannot be anything more or less than a is 3, b is 4, c is 7, d is 1, e is 5 and f is 7. Thus it is unclear which cyclotide represents the claimed invention of claim 4.

8. Claims 6 and 11 recite a cyclotide having a general formula wherein each of a to f represent the number of amino acid residues in each respective sequence and wherein a is about 6, b is about 4, c is 3, d is about 1, e is about 5, and f is about 8 with a SEQ ID NO: 5 in the parenthesis. It is unclear whether SEQ ID NO: 5 is an example or if SEQ ID NO: 5 represents the cyclotide of claim 6. If the latter case is true, then it is unclear how the amino acids can be as described above, since SEQ ID NO: 5 consists of a is 6, b is 4, c is 4, d is 1, e is 5 and f is 8. This reads that the amino acid residues have a set length of amino acids for a to f and cannot be anything more or less than a is 6, b is 4, c is 4, d is 1, e is 5 and f is 8. Thus, it is unclear which cyclotide represents the claimed invention of claim 5.

Rejection-35 U.S.C. 112, 1st

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 2-8 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature or the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

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(1) The nature of the invention:

The invention is drawn to a method of preventing on-growth of biological organisms on objects or living beings, comprising applying an agent on a surface of the object or living being.

(2) The state of the prior art:

The Merck manual indicates that bacteria are microorganisms that have circular double-stranded DNA cell walls. (see Merck manual, Bacteria Introduction). Additionally, the Merck manual indicates that antibacterials should be used only if clinical or laboratory evidence suggests bacterial infection. Use for viral illness or undifferentiated fever is inappropriate, subjects the patient to drug complications without any benefit, and contributes to bacterial resistance (see Merck manual, Selection and Use of Antibacterial Drugs, 1st paragraph). Furthermore, the Merck manual indicates that bactericidal drugs kill bacteria in vitro. Bacteriostatic drugs slow or stop in vitro bacterial growth but depend on body defenses to kill bacteria (see Merck manual, Selection and Use of Antibacterial Drugs, 3rd paragraph). Furthermore, resistance to an antibiotic may be inherent in a particular bacterial species or may be acquired as a result of mutations (see Merck manual, Antibiotic Resistance).

Additionally, the Mayo clinic indicates that periodontitis begins with plaque, and the definition of plaque is a soft, sticky, whitish matlike film attached to tooth surfaces, formed largely by the growth of bacteria that colonize the teeth. Additionally, the Mayo clinic indicates that the invisible, sticky film forms on the teeth when starches and

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sugars in food interact with bacteria normally found in the mouth...the plaque is removed every time a person brushes the teeth, but the plaque reforms quickly, usually within 24 hours (see MayoClinic.com, Causes, 1st paragraph). Furthermore, plaque that stays on the teeth longer than two or three days can harden under the gumline into tartar (calculus), and tartar can act as a reservoir for bacteria (see MayoClinic.com, Causes, 2nd paragraph). As indicated, there are bacteria normally found in the mouth. Additionally, the Merck manual indicates that pain is usually absent unless an acute infection forms in one or more periodontal pockets and abundant plaque along with redness, swelling, and exudate are characteristic (see Merck manual, Periodontitis, Symptoms, Signs, and Diagnosis). Furthermore, for all forms of periodontitis, the 1st phase of treatment consists of thorough scaling and root planning...if deeper pockets persist, systemic antibiotics can be used and surgical elimination of the pocket and recontouring the bone (see Merck manual, Periodontitis, Treatment).

The art recognizes that there are bacteria normally found in the mouth and elsewhere in the body and surfaces. The art provide guidance as how to alleviate bacterial infection, for example, periodontitis. Additionally, the Merck manual indicates that antibacterials should be used only if clinical or laboratory evidence suggests bacterial infection. However, none of the prior arts provide guidance as how to prevent the on-growth of biological organisms on objects or living beings.

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art:

Applicant's activity is based on the discovery that a cyclopeptide, cycloviolacin O2, extracted from the Sweet Violet, *Viola odorata* L, has an anti-fouling effect against larvae from barnacles (on-growth of barnacles on e.g. boat hulls) is inhibited and even prevented. Since the activity is based on preventing the on-growth of biological organisms on object or living beings, the predictability in the art is low. This is due to the fact that the art has recognized the difficulty in determining the patient population who are susceptible to bacteria growth, since normal bacteria exist in the human body (e.g., *E. coli*) and in the mouths. For example, antibacterials should be used only if clinical or laboratory evidence suggests bacterial infection (see above or Merck Index). Since the Mayo clinic indicates that periodontitis begins with plaque, and the definition of plaque is a soft, sticky, whitish matlike film attached to tooth surfaces, formed largely by the growth of bacteria that colonize the teeth. Additionally, the Mayo clinic indicates that the invisible, sticky film forms on the teeth when starches and sugars in food interact with bacteria normally found in the mouth...the plaque is removed every time a person brushes the teeth, but the plaque reforms quickly, usually within 24 hours (see MayoClinic.com, Causes, 1st paragraph). Furthermore, plaque that stays on the teeth longer than two or three days can harden under the gumline into tartar (calculus), and tartar can act as a reservoir for bacteria (see MayoClinic.com, Causes, 2nd paragraph). Furthermore, the Merck manual indicates that pain is usually absent unless an acute infection forms in one or more periodontal pockets and abundant plaque along with redness, swelling, and exudate are characteristic (see Merck manual, Periodontitis,

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Symptoms, Signs, and Diagnosis). Furthermore, for all forms of periodontitis, the 1st phase of treatment consists of thorough scaling and root planning...if deeper pockets persist, systemic antibiotics can be used and surgical elimination of the pocket and recontouring the bone (see Merck manual, Periodontitis, Treatment). Thus, in the example of periodontitis, it would be hard to determine the patient population, since bacteria is normally found in the mouth.

The claims do not identify the patient population, therefore, the claims imply that anyone can be protected against on-growth of biological organisms. Additionally, the claims imply that any objects can be protected from on-growth of biological organisms. However, the Applicant has not shown who will be susceptible to bacterial growth (on-growth of biological organisms). There are too many variables between the patient populations and the objects or surfaces of the objects, thus, it clearly shows the unpredictability of the art.

(5) The breadth of the claims:

The claims are drawn to a method of preventing on-growth of biological organisms on objects or living beings, comprising applying an agent on a surface of said object or living being, wherein the agent comprises at least one cyclotide, and a suitable carrier medium.

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(6) *The amount of direction or guidance presented and (7) The presence or absence of working examples:*

Although the specification provides guidance on how to administer the compound, it is unclear as to when to administer the compound and the patient population. The specification discloses example of the larval bioassay and the on-growth inhibiting effect of cycloviolacin O2 on vessel hulls (see paragraph [0045] and Examples). The specification discloses the on-growth inhibiting effect of cycloviolacin O2 on settlement and mortality of *B. improvisus*, and discloses that the settlement was inhibited in a dose-dependent manner (see Example 2). Further, the specification discloses that extraction and fractionation of plant material (both fraction P and I) were tested for on-growth inhibiting effect. Fraction P inhibited in a dose-dependent manner; Fraction I also inhibited settlement, but only at 0.1 mg/ml (see Example 3). Further, the specification discloses that Fraction P was field tested in a marine paint in two different concentrations, and no settling of barnacles was observed for the dishes coated with paint containing Fraction P (see Example 4).

The specification has not provided guidance in the way of a disclosure to how to determine apply this on living beings and individuals that need protection against on-growth of biological organisms. Applicant's activity is on the premises of the cyclotides inhibiting barnacle growth on marine physical objects, such as barnacles on marine structure, micro-organisms forming bio-films on medical equipment, and on living animals (see paragraph [0001]). However, both the specification and the claims do not disclose how to prevent the on-growth of biological organisms or living beings as

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pertaining to bacterial growth. Additionally, the specification does not disclose how to determine the patient population (as in living beings) to prevent on-growth biological organisms. Since bacteria are normally found in the human body and in the mouths, it would be difficult to prevent the on-growth of biological organisms in the mouth and in the human body. Additionally, the base claim 11 recites that "applying an agent on a surface of object or living being would prevent on-growth of biological organisms." As stated in the statement of statutory bases for 112, 1st paragraph (enablement), "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention." However, the specification does not provide guidance as how to use the claimed invention. For example, if a meat is sitting out at room temperature, but the agent of the claimed invention is applied to the surface of the meat, then according to the Applicants invention, that would prevent "on-growth of biological organisms". This implies that the meat will not "spoil". Additionally, any living or dead tissue applied with the agent of the instant invention would never have bacterial growth. Additionally, since the cyclotide is made up of amino acids, the protein would naturally degrade/decompose or change chemically. Thus, one application of the instant invention cannot go on indefinitely. The agent of instant applicant must be reapplied, thus the on-growth of biological organisms cannot be prevented indefinitely. Furthermore, if the agent of instant invention is applied to the teeth to prevent

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periodontitis, the saliva would wash off the agent. Thus, one single application would not continuously prevent the on-growth of biological organisms in the mouth.

There is no clear guidance as to how to determine the patient population and how and when to apply the agent to the surface of the object or living beings. Since the prior art is still unclear as to who are susceptible to bacterial growth, more guidance is necessary.

(8) The quantity of experimentation necessary:

Since it is uncertain to predict the patient population who are susceptible for bacterial growth, and the Applicant have not provided the appropriate time frame at which the compound should be administered, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine if the cyclotides would be effective in preventing the on-growth of biological organisms on object or living beings.

Please note that the term "prevent" in an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "therapeutic" or "treat" or "alleviate", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes)- including preventing such disorders as on-growth of biological organisms (and read to mean bacterial growth), which is clearly not recognized in the medical art as being totally preventable condition.

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11. Claims 2-8 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

12. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

13. Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

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"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

14. The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

15. In the instant case, the claims are drawn to a method of preventing comprising applying an agent on a surface of said object or living being, said agent comprising at least one cyclotide, and suitable carrier medium. The generic statement cyclotide does not provide ample written description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

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16. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 11 is broad generics with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of peptide or a peptide-like molecule that can form cyclotides (cyclic peptide (see paragraph [0003]). It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. The specification is void of organic molecules that functions as a peptide-like molecule that qualify for the functional characteristics claimed as a peptide or a peptide-like molecule or other peptidic molecules that can be cross-linked to form a cyclic peptide, and other synthetic peptide or peptide-like molecule that can function as cyclic peptides.

17. The specification is limited to the peptide or peptide-like molecules that belong to the same class of cyclopeptide, cycloviolacin O2. The specification discloses that cycloviolacin O2 consist of almost 50 members (see paragraph [0008]). The

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specification further discloses that cycloviolacin O2 has an antifouling effect against barnacles (see paragraph [0009]). Additionally, the specification discloses examples of cyclotides (about 45 that all have 6 cysteine residues with varying lengths of loops in between the cysteine residues) usable for the prevention of on-growth of biological organisms (see paragraph [0032]). The working example only describes the cyclotide cycloviolacin O2 (see paragraph [0051]). The specification does not describe any other cyclotides, such as synthetic amino acids comprising non-natural amino acids (i.e. D-amino acids, or beta amino acids and so on) or any other type of peptide or peptide-like molecule that act as cyclotides that are formed from organic molecules that act like a peptide or peptide-like molecule. Additionally, the specification does not disclose any other cyclic peptides that can be formed by any peptide molecules. For example, there are varying lengths, varying amino acid compositions, and numerous distinct qualities that make up the genus. The specification does not disclose any cyclic peptides that may only have 3 cysteine residues. Additionally, it is known in the art that cyclization of linear peptides increase potency, selectivity and stability. Grasso et al teach methods and compositions containing leptin peptides (see abstract) and leptin analogs with increase in potency and stability of biologically active leptin-related peptides (see column 36, lines 38-40). Furthermore, the reference teaches that another strategy which can be used to develop peptide analogs of increased potency, selectivity and stability relies on the introduction of covalent cross-links into a peptide sequence to conformationally and topographically constrain the peptide backbone. Macrocyclization is often accomplished by forming an amide bond between the peptide N- and C-

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termini, between a side chain and the N- or C-termini or between two amino acid side chains (see column 36, lines 53-61). Thus, any peptide can be formed into a cyclic peptide and the specification does not disclose all possible cyclotides (e.g., 10mer, 20mer, 45mer, 100mer, 200mer and so on). There is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed.

18. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984)

(affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Rejection-35 U.S.C. 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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20. Claims 2-8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Craik et al (WO 01/27147).

21. The instant claims are drawn to a method of preventing on-growth of biological organisms on objects or living beings, comprising applying an agent on a surface of said object or living being, an agent comprising at least one cyclotide, and a suitable carrier medium, wherein the cyclotide have a general formula and a, b, c, d, e and f represent the number of amino acid residues in each respective sequence and each of a to f may be the same or different and range from 1 to about 20 and claims 3-7 further limit the length of a-f.

22. Craik et al teach a molecular framework also referred to as "cyclotide" (see p. 19, lines 25-26). The reference teaches the heterologous amino acids inserted in the molecular framework useful in the treatment of pain or a stroke...anti-inflammatory agent, antibiotic activity...microbial activity, fungal activity...(see p. 22, lines 4-10). Additionally, the reference discloses that the use of the molecular framework with or without particular amino acids inserted or substituted thereon for the treatment of or prophylaxis of disease conditions in animals, mammals (including humans) and plants (see abstract and p. 7, lines 22-25). This reads on claim 11. Furthermore, the reference discloses that the molecular framework may be selected to treat plants against pathogen infestation and mammals including humans from viral or microbial infection (see p. 14, lines 11-14). Additionally, the composition comprising cyclic molecular framework molecules and pharmaceutically acceptable carrier and/or diluent is disclosed (see p. 7, lines 27-29). Further, the reference discloses that applications for

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the cyclotide include pharmaceuticals and agrochemicals (see Example 6). This further reads on claim 11. Furthermore, the reference discloses sequences for cycloviolacin 01-11, H1, kalabata B5, circulin A-B, cyclopsychotride A, violapeptide 1, kalabata B1-B4, varv peptide A-H, and other cyclotides (Table 5). The reference discloses SEQ ID NO:2 which has the sequence for cycloviolacin 02:

CGESCVWIPCISSAIGCSCKSKVCYRNGIP (see p. 2 of Sequence listing). This meets the limitations of claims 2-5, 7-8 and 11. Furthermore, the reference discloses cyclotide wherein a, b, c, d, e and f are (a) from 1 to about 20; (b) from 1 to about 10; (c) a is from about 3 to about 6, b is from about 3 to about 5, c is from about 2 to about 7, d is about 1 to about 3, e is about 3 to about 6 and f is from about 4 to about 9; (d) a is about 3, b is about 4, c is from about 4 to about 7, d is about 1, e is about 4 or 5 and f is from about 4 to 7; (e) a is about 6, b is about 5, c is about 3, d is about 1, e is about 5 and f is about 8 (see pp. 3-6). This meets the limitation of claims 2-6. It is noted that claim 6 has been rejected over the prior art, even though the reference does not disclose exact amino acid length as claimed. However, the claims utilize the term "about" when discussing the amino acid length. The term "about" allows for some tolerance in the ranges disclosed. In In re Ayers, the Federal Circuit held that "at least about 10%" was anticipated by a reference that disclosed "about 8%" because the term "about" allowed for some tolerance. In re Ayers, 154 F.2d 182, 185 (Fed. Cir. 1946). Similarly, in Johnson and Johnson v. W. L. Gore & Associates, Inc., the Court allowed for about "1.2" to be inclusive of 1.0. See Johnson and Johnson v. W. L. Gore & Associates, Inc., 436 F.Supp. 704, 728-729 (Fed. Cir. 1977). Thus, the term "about" implicitly discloses

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some variability even though the specification may not literally cite this variability. Thus, the disclosure of an amino acid length of "about" 4 encompasses an amino acid length of "about" 5, as disclosed in the prior art.

Conclusion

23. No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982.

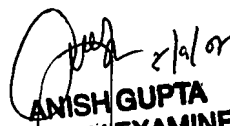
The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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